

# Quality assessment in Belgian ST elevation myocardial infarction patients: results from the Belgian STEMI database

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## Abstract

The present report describes the quality of care, including in-hospital mortality for more than 22,000 STEMI patients admitted in 60 Belgian hospitals for the period 2008-2016. We found a strong increase in the use of primary PCI over time, particularly for patients that were admitted first in a non-PCI capable hospital, reaching a penetration rate of >95%. The transition of thrombolysis to transfer for pPCI in the setting of a STEMI network was, however, associated with an increase of the proportion of patients with prolonged (>120min) diagnosis-to-balloon time (from 16 to 22%), suggesting still suboptimal interhospital transfer. The in-hospital mortality of the total study population was 6.5%. For non-cardiac arrest patients in-hospital mortality decreased from 5.1% to 3.7%, while it increased for cardiac arrest patients from 29 to 37%. The observation that quality indicators (QI's), such as modalities and timing of reperfusion therapy, were associated with lower levels of mortality, underscores the potential of QIs for STEMI to improve care and reduce unwarranted variation and premature death from STEMI.

## Background

The current guidelines for the management of ST-segment elevation myocardial infarction (STEMI) recommend primary percutaneous coronary intervention (pPCI) as the preferred treatment strategy if it can be conducted in a timely fashion by an experienced catheterisation team.<sup>1,2</sup> However, because of logistical restraints, PCI can only be offered in less than 50% of Belgian hospitals. This has formed the basis of the development of STEMI networks with pre-arranged rapid transfer protocols between community hospitals and PCI centres.<sup>3,4</sup> To ensure that the benefits of these concepts are implemented in daily practice, the Belgian STEMI registry has been launched in 2007. Within this registry, quality indicators are imbedded which allows to assess quality of care in Belgium. Both process as outcome indicators have been defined within the college of cardiology and the working group of acute cardiology based upon international recommendations.<sup>5</sup>

The present report describes the quality of care, including in-hospital mortality for STEMI patients admitted in Belgian hospitals for the period 2008-2016.

## Methods:

The data were collected for consecutive STEMI patients from 60 hospitals between January 2008 until December 2016.

STEMI patients were defined as patients with symptoms suggestive of ACS, with a significant ST-T segment deviation (ST elevation of more than 0.1mV in 2 or more continuous electrocardiogram (ECG) leads, or new left bundle branch block, or ST segment depression 0.1mV or greater in 2 of the precordial leads V1-V4) and with elevated biomarkers of myocardial necrosis.

Collection of data was carried out by electronic web-based registry that is governed by an independent software company specialised in electronic data capture solutions (Lambda-plus- website: <http://www.lambdaplus.com>). An external commission audited the data validity of 5% of the patient files, and the database was registered on clinicaltrials.gov (NCT00727623). The database was approved by the Belgian Data Protection Agency. Informed consent was obtained from all patients or their legal representatives.

A number of baseline characteristics for each patient was included which allowed to stratify the patients according to a previous validated TIMI risk score: age, gender, collapse with cardiopulmonary resuscitation (CPR), history of coronary artery disease (CAD) or peripheral artery disease (PAD), location of infarction, total ischemic time, age, hemodynamic status on admission, history of atherosclerotic disease, history of hypertension or diabetes. Since 2015 also data on smoking habits and renal function are gathered. Following quality parameters were registered and are based upon the European QI's for STEMI:

a) Types of reperfusion strategy: thrombolysis (TL), percutaneous coronary intervention (PCI) or no reperfusion.

b) Time delays between diagnosis and treatment, subdivided into diagnosis-to-balloon time (time between first ECG with STEMI diagnosis and the balloon inflation) and the door-to-balloon (time

between arrival in the PCI centre and the balloon inflation). The exact time delays were recorded from 2010.

c) medication at discharge (statin, P2Y12 inhibitors, ACE/AT inhibitors, beta-blockers) was recorded from 2015.

d) in-hospital death from all causes as late as 30 days after admission. Vital status was assessed in the final hospital before home discharge

### Statistical Analysis

Continuous variables are presented as the mean values with corresponding standard deviation (SD). Comparisons between groups were made with an unpaired t-test. The differences between proportions were assessed by chi-squared analysis. Independent determinants of in-hospital death were determined by means of multiple logistic regression analysis and reported as odds ratios (ORs) and 95% confidence intervals (CIs). Following factors were included in this analysis: age, gender, weight, history of CAD or PAD, arterial hypertension, diabetes mellitus, Killip class, blood pressure and heart rate on admission, infarct location, cardiac arrest with resuscitation, total ischemic time. For all analyses, a value of  $p < 0.05$  was considered statistically significant.

## Results

### Study population:

The total study population consisted of 22149 patients with an annual enrolment between 2400 and 2700 pts. The regional distribution of the enrolment is depicted in figure 1. Of the total population, 9463 patients (43%) were admitted to a community hospital and 12686 (57%) to a PCI-capable hospital. Two third of the patients are admitted in the hospital by means of the Emergency medical services (EMS) and 60% were treated within 4 hours of onset of pain. Cardiac arrest was present in almost 10% of the STEMI patients.

### Process indicators

Changes in reperfusion therapy over time are depicted in figure 2A-B. There was a profound shift towards more primary PCI from overall 81% to 94%. This trend was particularly observed in the community hospitals. Transfer rate for primary PCI in community hospitals increased from 64% to 95% at the cost of less thrombolysis and less conservative treatment ( $p<0.0001$ ). Also in PCI capable hospitals there was a further increase of primary PCI from 92% to  $> 95%$  ( $p<0.001$ ).

The average diagnosis-to-balloon time was  $98 \text{ min} \pm 143$  with a median of 70 min. DTB $>120$ min was present in 14% of the patients that were admitted directly in a PCI centre and in 27% of the patients that were initially admitted in a non-PCI centre. Patient who were admitted with EMS were less likely to have prolonged DTB times (19% vs 28%). Over time the proportion of patients with prolonged DTB ( $>120$ min) increased slightly with lowest value of 16% in 2010 and the highest value of 22% in 2015 (see figure 3)

The average door-to-balloon time was  $76 \pm 137 \text{ min}$  with a median of 47min. Prolonged door-to-balloon time ( $>60$ min) was present in 36%. Patients with prolonged diagnosis to balloon time have also longer door-to-balloon times ( 137 min in patients with DTB $>120$ min vs 56 min in patients with DTB $<120$ min ,  $p<0.001$ )

Discharge medication were prescribed according to European guidelines. P2Y12 inhibition was prescribed in 96% of the patients of which 12% received clopidogrel, 30% prasugrel and 58% ticagrelor. Statin were prescribed in 94% of the STEMI patients. Beta-blocker and ACE inhibition were prescribed 87% and 78%, respectively

### Outcome indicator

The in-hospital mortality of the total study population was 6.5%. In hospital mortality in the patients without cardiac arrest was 3.6% whereas the mortality of cardiac arrest patients was 30%. Despite improvements in baseline risk profile and higher use of pPCI since 2010, there was no decrease in the in hospital mortality for the total population which ranged between 5.8 and 7.7% (see fig 3). However, for non-cardiac arrest patients in-hospital mortality decreased steadily from 5.1% to 3.7%, while it increased for cardiac arrest patients from 29 to 37%.

Logistic regression analysis identified cardiac arrest (OR: 10), Killip class $>1$  (OR:6), high age (OR: 1.07), prolonged( $>12$ h) ischemia (OR: 1.9), no reperfusion therapy (OR:1.7), presence of peripheral artery disease (OR:1.7) and diabetes (OR: 1.4) as the independent predictors of in hospital mortality.

## DISCUSSION

Using a nationwide clinical database, comprising an analytical cohort of more than 20 000 STEMI patients admitted in 60 Belgian hospitals, the present report describes the evolution of predefined quality indicators for STEMI management in the period between 2008–2016. We found a strong increase in the use of primary PCI over time, particularly for patients that were admitted first in a non-PCI capable hospital, reaching a penetration rate of >95% which is in line with European recommendations. The transition of thrombolysis to transfer for pPCI in the setting of a STEMI network was, however, associated with an increase of the proportion of patients with prolonged diagnosis-to-balloon time, particularly in the early phase of the transition (2012-2015). On average 27% of the patients that were admitted firstly in a non-PCI centre had a prolonged diagnosis-to-balloon time (>120min) which is better than US experience (49%) but worse than the UK experience (8%).<sup>6,7</sup> Longer diagnosis-to-balloon times in patients who were initially admitted in non-PCI centres suggest that the organisation for interhospital transport is suboptimal. Indeed, there are still hospitals without PCI facilities that rely on the PCI hospital's MUG/SAMU facilities to pick up the patients, obviously tremendously adding to the delays. The most optimal transfer policy is the direct transfer of STEMI patients (from home or from community hospital) to the nearest PCI capable hospital. On the other hand, prolonged diagnosis-to-balloon times were also associated with prolonged door-to-balloon times, suggesting that the internal organisation within the PCI centre is suboptimal. Early notification of the catheterisation laboratory team, preferentially by EMS and direct transfer to the cath lab, bypassing the emergency room are a prerequisite to obtain target door-to-balloon times.<sup>8</sup>

With regard to secondary prevention treatment, the recorded quality indicators (discharge medication) scored high with values above 90% for the IA recommended pharmacologic treatments (cf statine, P2Y12).

The increased use of primary PCI, together with the improvement of baseline risk profile might explain a steady but modest decrease of in hospital mortality at least in non-cardiac arrest patients which is in line with other European registries<sup>9,10</sup>. It is however conceivable that the observed prolongation in time delays for primary PCI might have attenuated the mortality benefit expected from increased pPCI use in our registry.

For cardiac arrest patients, which constitutes 10% of the study population, we observed a slight increase in mortality which might be related to a more aggressive treatment/inclusion over time of severely unstable cardiac arrest patients with catastrophic prognosis. The relatively high number of cardiac arrest patients (=10%) in our study population has caused mortality rates that are slightly higher than contemporary European registries that enrolled mostly <5% of cardiac arrest patients.

The identification of independent predictors of mortality revealed that both patient characteristics such cardiac arrest, hemodynamic instability, peripheral artery disease as factors related to quality of management such as modalities and timing of reperfusion therapy determine the outcome.

The observation that high levels of performance are associated with low levels of mortality, underscores that the QIs for AMI are applicable and valid and have the potential to improve care and reduce unwarranted variation and premature death from AMI.

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Figure 1

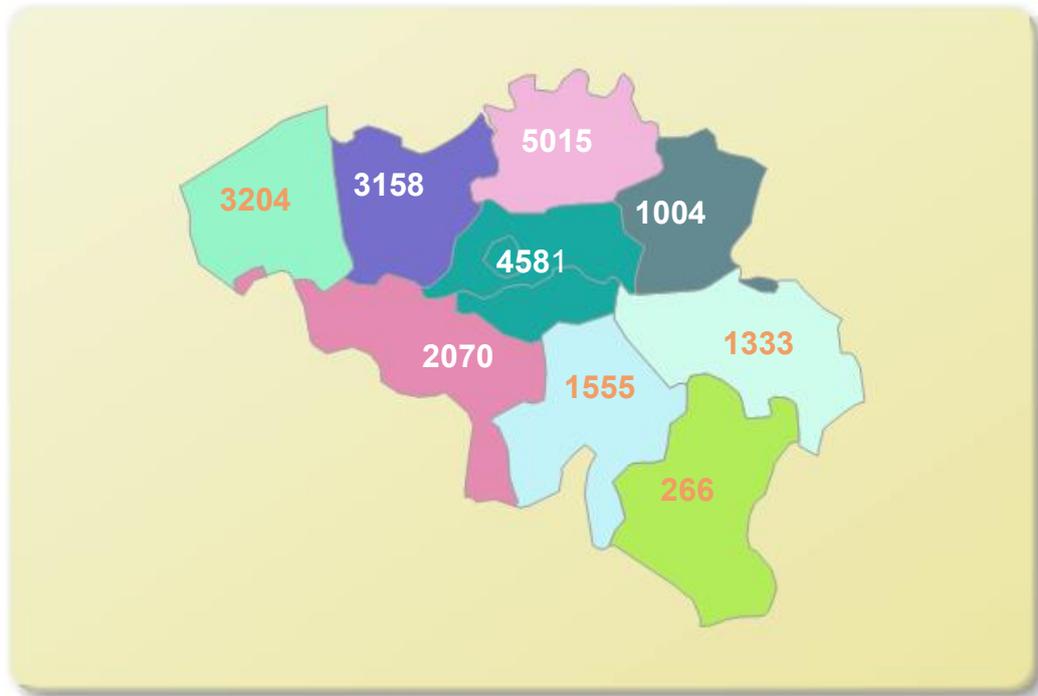


Fig 2 A: Reperfusion therapy in PCI capable hospitals

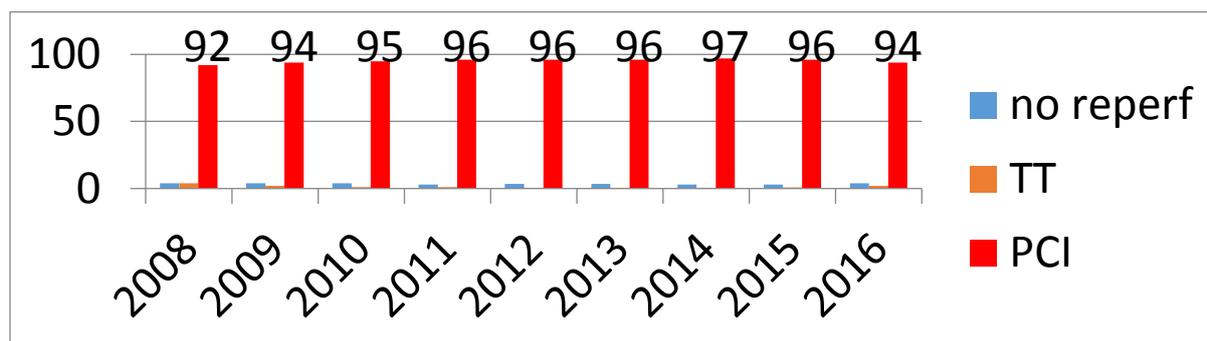
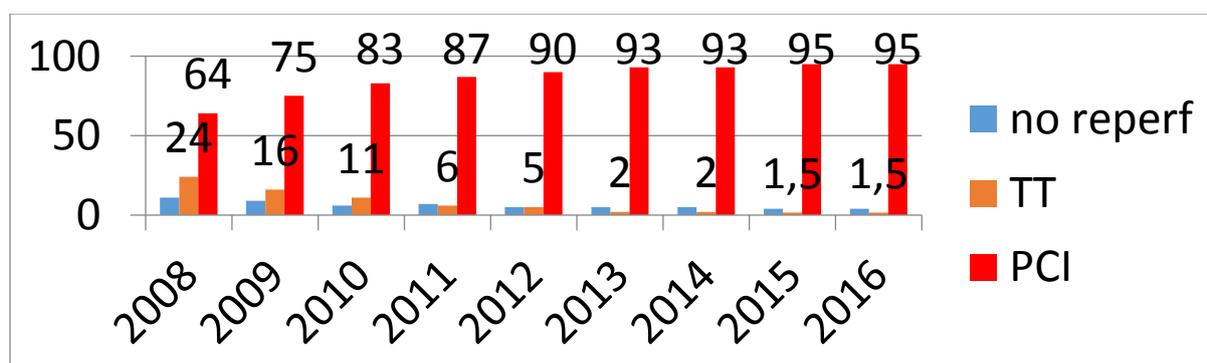


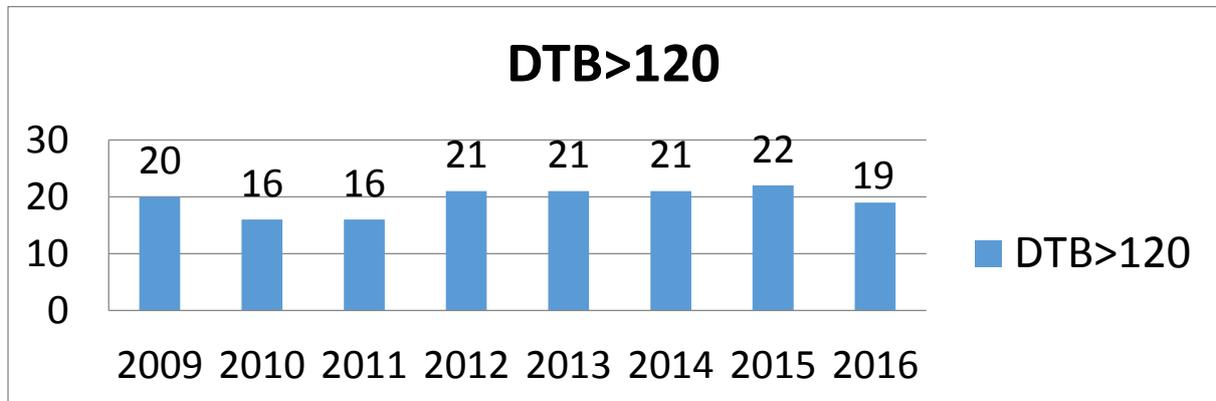
Fig 2B: Reperfusion therapy in community hospitals



Values are represented as percentages.

Abbreviations: PCI , percutaneous coronary intervention; TT, thrombolysis

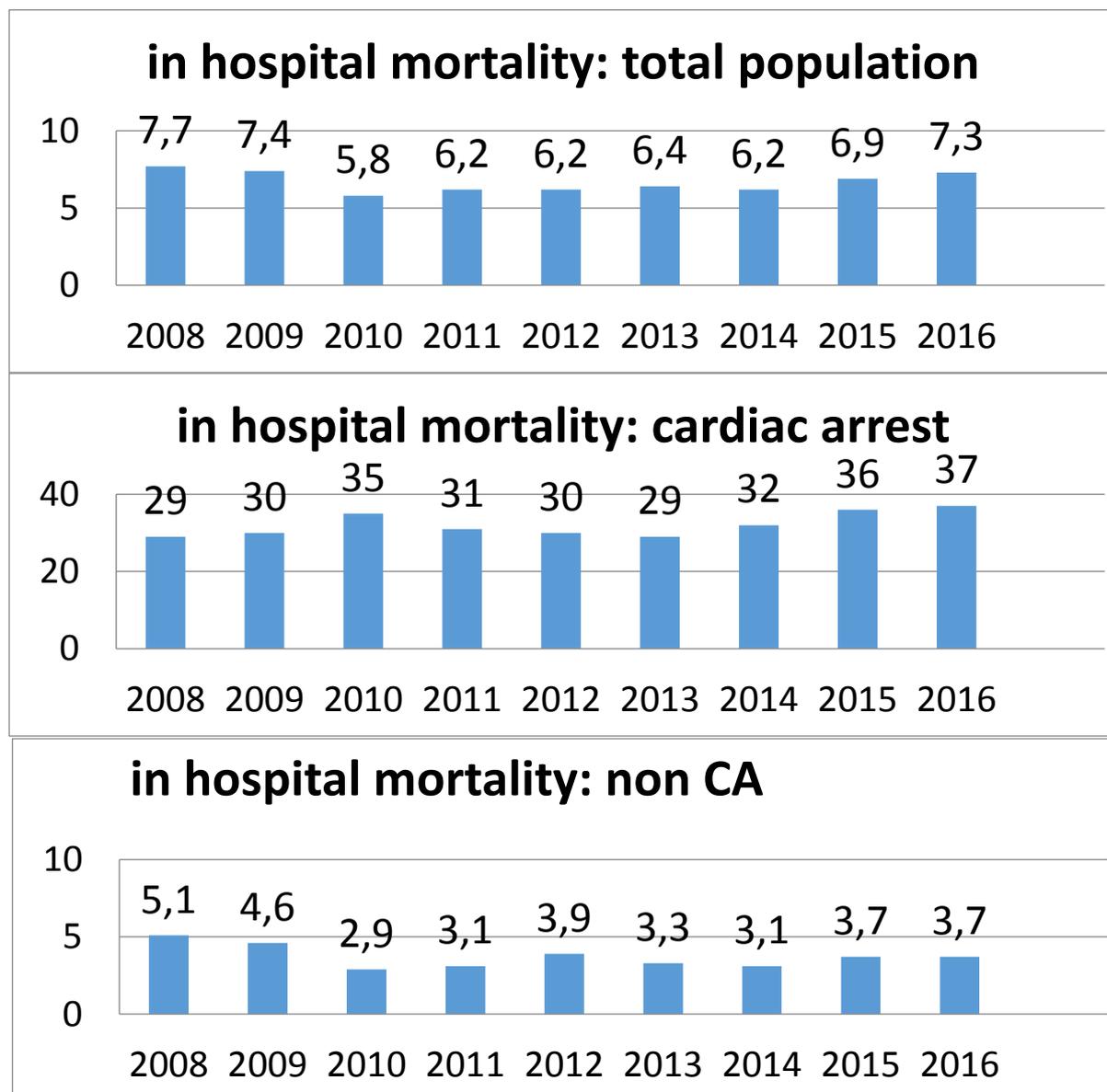
Figure 3



Values are represented as percentages.

Abbreviations: DTB, diagnosis to balloon time

Figure 4: Trends in mortality



Abbreviations : CA, cardiac arrest